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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,897	02/10/2004	Donald B. Axworthy	110186.53659C23	2183

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/775,897

Applicant(s)

AXWORTHY ET AL.

Examiner

David A Saunders, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

The preliminary amendment of 2/10/04 has been entered. Claims 16-19 are pending and under examination.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

On 2/10/04 applicant submitted copies of numerous declarations and supplemental declarations pertaining to parent applications 08/122,979 and 07/995,381; also a copy of a revocation and substitute power of attorney paper from parent application 08/788,339 was submitted. The Office has no idea of the relevance of these papers and no idea as to which is intended to be the declaration for the instant continuation application. The Office has no idea as to who the inventors are; a declaration for 08/122,979, executed on 11/15/93, lists Reno, Theodore and Gustavson; also four separate declarations for 08/122, 979, executed on the same date, were submitted by Reno, Theodore, Gustavson and Axworthy.

Currently the Office data in PALM/PAIR lists Axworthy, Theodore, Gustavson, Reno, Mallett, Hylarides and Fritzberg as inventors.

Applicant must file a communication indicating which of the previously executed declarations is intended, or else submit a newly executed declaration. Applicant must also indicate in the communication what the proper inventorship is.

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The disclosure is objected to because of the following informalities: In the continuation data (inserted at page 1, by the preliminary amendment 2/10/04), applicant must update the status of allowed application 09/920,454.

Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

Claims 16-19 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Since the record is so infusing (see objection to declaration/oath supra) as to who the proper inventors are, the examiner cannot determine whether the seven inventors listed in PALM/PAIR as the inventive entity (see objection to declaration/ oath supra) are, in fact, the proper inventors.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 18-19 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 5-6 of prior U.S. Patent No. 5,608,060. This is a double patenting rejection.

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Instant dependent claims 18-19 recite precisely the same limitations, with respect to R3, R4 and n, as do issued dependent claims 5-6.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4 of U.S. Pat. No. 5,608,060.

In instant claim 16, the formula for L reads precisely as that for L in issued claim 4. The only difference is in the definition of n, which is "0-4" instantly and "0-5" as issued. Issued claim 4 is thus broader than, but clearly encompasses instant claims 16-17; a disclaimer is thus required in order to assure that Pat 5,608,060 and any issued instantly will remain commonly owned.

Claims 16-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,955,605. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 16 and issued claim 1 recite the same structural

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formula having the generic linker L. Instant claim 16 defines the structural features of L, while the issued claim recites in vivo functional features of L with respect to serum stability. These functional features, however can be clearly correlated with the instantly recited structural features of L -- e.g. see claim 1 of related Pat. 6,709,652 for evidence of this relationship. Also see cols. 24-32 of '605 for similar evidence. The more generic issued claim therefore encompasses instant claim 16. A disclaimer is required to assure that issued Pat. '605 and any issued instantly shall remain commonly owned.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rosebrough (5,807,879) is cited as the closest art. The linker shown in claim 1 of Rosebrough does not correspond to that instantly defined in claim 16.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/LR
November 12, 2004

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
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